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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/527,656

12/30/2005

Malan de Villiers

SF-112

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EXAMINER

GANESAN, SUBA

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

09/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/527,656 | Applicant(s) DE VILLIERS, MALAN | |
| | Examiner Suba Ganesan | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/30/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 15-16, 19, 21-22, 26 and 29-32 rejected under 35 U.S.C. 102(b) as being anticipated by Laure (U.S. Pat. No. 4,040, 130).

3. Laure discloses an arthroplasty implant comprising a first component 1 defining a concave surface 6 and having a first connector 7 connecting the first component to the body member, a second component 3 defining a convex surface 16 and having a second connector 23,22 connecting the second component to a second body member, and an intermediate component 2 (see fig. 1). The concave surface of the first component and the convex surface of the intermediate component are complementally spherically curved (see figs. 7-8). The first and second components are capable of translation and articulation relative to the intermediate component. The intermediate component is made of high molecular weight polyethylene (col. 2 lines 42-54). The first and second connector each include a projecting post (see fig. 1). The intermediate component 2 includes a laterally outward facing projection 12 and the first component includes a laterally inward facing recess (see fig. 4 and 7-8).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 17-18, 20, 24-25, 28, 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laure (U.S. Pat. No. 4,040, 130).

6. Laure is explained supra. However, Laure lacks specific disclosure of a multiple radii of curvature for the convex and concave surfaces of the second component and the intermediate component, respectively. It would have been obvious to one of ordinary skill in the art to create an oblong (i.e. radii of curvature which differ in mutually orthogonal directions) surface of the intermediate component and the second component, since doing so would shorten the prosthesis and reduce the amount of material needed for fabrication of the implant. One of ordinary skill in the art would have been able to predict the results of such a modification.

7. Laure further lacks specific disclosure of grade 5 titanium with a titanium nitride finish. However, use of this material would have been obvious to one of ordinary skill in the art since doing so is simply selecting from a known range of suitable biocompatible implant materials.

8. Laure lacks a central projection on the concave surface of the first component and a central opening on the convex surface of the intermediate component. It would have been obvious to one of ordinary skill to provide such a modification, since it has

been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein* 8 USPQ 167.

9. Laure appears to lack disclosure of the peripheral edges of the first component and the intermediate component contacting at the maximum limit of motion. Such a feature would be obvious to one of ordinary skill in the art, since a well-known limit of articulation is the contact of two components.

10. Laure lacks disclosure of the implant as a metatarsophalangeal joint prosthesis. It would have been obvious to one of ordinary skill in the art to modify the implant of Laure to be a metatarsophalangeal implant, since doing so simply requires an adjustment in size to match the native bone geometry. Both the joint prostheses include articulating components, so one of ordinary skill could easily predict the results of changing the size of the implant of Laure to match the geometry of the particular joint.

1. Claims 27, 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laure (U.S. Pat. No. 4,040, 130) in view of Ostiguy Jr. et al. (6,152,961).

2. Laure is explained supra. However, Laure lacks an annular wall with an undercut and an intermediate component with an annular rib. Ostiguy Jr. teaches the use of a groove-mating groove type connector for attaching a polymeric liner to a ball and socket type joint prosthesis. Therefore it would have been obvious to one of ordinary skill in the art to modify the implant of Laure with an annular wall with an undercut and an intermediate component with an annular rib as taught by Ostiguy Jr. for the purpose of securing the components relative to one another.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suba Ganesan whose telephone number is 571-272-3243. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDG 9/4/2007



BRIAN E. PELLEGRINO
PRIMARY EXAMINER